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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,219	06/29/2000	Ivan Tomka	24301	7685

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WASHINGTON, DC 20005

EXAMINER

NORDMEYER, PATRICIA L

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 08/04/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/606,219

Applicant(s)

TOMKA ET AL.

Examiner

Patricia L. Nordmeyer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-21 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-21 and 23-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 27, 2003 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12, 14, 17, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stroud (USPN 5,554,385).

Stroud discloses a soft capsule (Column 1, lines 41 – 42), wherein the capsule is made from 3 – 60% high amylose starch, 30% glycerol (a softener) and 6% water (Column 4, lines 59 – 63) that is homogenized (Column 3, lines 22 – 25). Amylopectin makes up 50% of the starch (Column 2, lines 17 – 28). Since Stroud contains the selected materials of amylopectin and glycerol, it is inherent that the starch would have a viscosity between 40 ml/g and 60 ml/g.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18 – 20 and 28 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stroud (USPN 5,554,385).

Stroud discloses a soft capsule (Column 1, lines 41 – 42), wherein the capsule contains 3 – 60% high amylose starch, 30% glycerol (a softener) and 6% water (Column 4, lines 59 – 63). Amylopectin makes up 50% of the starch (Column 2, lines 17 – 28) in the capsule, which has a thickness of 0.03 inch (Column 3, lines 44 – 45). Since Stroud contains the selected materials of amylopectin and glycerol, it is inherent that the starch would have a viscosity between 40 ml/g and 60 ml/g. However, Stroud fails to disclose an elongation of rupture of at least 100%, preferably at least 160%, and even more preferred 240% at 25 C and 60% relative air humidity, the body shape with a strength of at least 2 MPa, preferably a strength in the range of 3.5 MPa to 8 MPa and even more preferred from 4 MPa to 6.5 MPa and a capsule with a thickness between 0.1 and 2mm, preferably between 0.2 and 0.6 mm.

One of ordinary skill in the art would have recognized the claimed capsule would have an elongation of rupture of at least 100%, preferably at least 160%, and even more preferred 240% at 25 C and 60% relative air humidity, the body shape with a strength of at least 2 MPa,

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preferably a strength in the range of 3.5 MPa to 8 MPa and even more preferred from 4 MPa to 6.5 Mpa since Stroud teaches a soft capsule containing the same parameters as the claimed invention. Therefore, one of ordinary skill in the art would readily determined the optimum strength and elongation of rupture depending on the desired end results in the absence of unexpected results.

Stroud discloses the claimed invention except for the thickness of the capsule. It would have been obvious to one having ordinary skill in the art at the time the invention was to have a wall thickness between 0.2 and 0.6 mm, since it has been held that where the general conditions of a claim are discloses in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).

6. Claims 13, 16 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stroud in view of Overholt (USPN 6,258,380).

Stroud discloses the claimed invention above except for the mass additionally containing a lubricant and releasing agent selected from the desired group, the mass containing an aggregate in a weight range between 3.5% and 15% from the desired group and the aggregate weight rang being between 5 and 8% by weight.

Overholt teaches a plasticizer, lubricant, made from glycerin, sorbitol or maltitol (Column 7, lines 48 – 50) and an aggregate chosen from cellulose, vegetable gums, saccharides

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and silicon dioxide (Column 7, lines 54 – 58) in a weight percent of 0.5 to 6.5% (Column 7, lines 59 – 61) in a sheath of capsule for the purpose of making a sheath of a soft capsule that has a non-sticky consistency and is flexible.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the lubricant and aggregate in Stroud in order to make a sheath of a soft capsule that has a non-sticky consistency and is flexible as taught by Overholt.

7. Claims 15, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stroud in view of Nakajima et al. (USPN 5,098,606).

Stroud discloses the claimed starch mass above except for the mass containing glycerine monostearate and lecithin in a weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1.

Nakajima et al. teaches a phospholipid, lecithin, (Column 3, lines 14 – 20) and glycerine monostearate as a nonionic surfactant (Column 3, lines 21 – 28) in a ratio of a phospholipid to surfactant of 9.5:0.5 to 1:9 (Column 3, lines 54 – 56) in a emulsified composition used for the administration of drugs for the purpose of incorporating the drug quickly into the body from the blood stream of the patient.

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It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the lecithin and glycerine monostearate in Stroud in order to incorporate the drug quickly into the body from the blood stream of the patient as taught by Nakajima et al.

Nakajima et al. discloses the claimed invention except for the weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1 of glycerine monostearate and lecithin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the weight ratio of the glycerine monostearate and lecithin, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stroud in view of Patel et al. (USPN 6,248,363).

Stroud discloses the claimed starch mass above except for the mass containing the shape body consisting of a multi-layered film and that at least two of the layers have different chemical composition.

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Patel et al. teach multi-layered film, multi-coating, on soft capsules made of different materials (Column 42, lines 13 – 58) for the purpose of delivering pharmaceutical active ingredients to the user of the capsule.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the multi-coated capsule in Stroud in order to deliver pharmaceutical active ingredients to the user of the capsule as taught by Patel et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Nordmeyer whose telephone number is (703) 306-5480. The examiner can normally be reached on Mon.-Thurs. from 7:00-4:30 & alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on (703) 308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Patricia L. Nordmeyer  
Examiner  
Art Unit 1772

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pln

July 30, 2003

*Nasser Ahmad*  
NASSER AHMAD  
PRIMARY EXAMINER  
*Acting SPE*